Atty. Dkt. No. 029860-0154

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Angel LOPEZ, et al.

Title: METHOD OF MODULATING LEUKEMIC CELL AND EOSINPHIL ACTIVITY WITH MONOCLONAL ANTIBODIES

Appl. No.: 10/774,887

Filing Date: 2/9/2004

Patent No.: 7,427,401

Grant Date: 9/23/2008

Examiner: Prema Maria Mertz

Art Unit: 1646

Confirmation Number: 8791

REQUEST FOR RECONSIDERATION OF DISMISSAL OF REQUEST FOR RECONSIDERATION OF PATENT TERM ADJUSTMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This is a request for reconsideration of the dismissal dated September 28, 2009 of the Request for Reconsideration of Patent Term Adjustment filed in the captioned application (hereinafter "Dismissal"). The fee required by 37 C.F.R. § 1.181(e) was submitted with the original Request and receipt thereof is acknowledged at page 1 of the Dismissal. If a request for reconsideration is not appropriate, then this present request is a petition under 37 CFR sections 1.181, 1.182, and 1.183.

In the Dismissal, the PTO refuses to follow a decision of the United States District Court for the District of Columbia with regard to Patent Term Adjustment (PTA).

U.S. Patent Law, specifically 35 U.S.C. 154(b)(4)(A), provides:
"An applicant dissatisfied with a determination made by the Director under paragraph (3) shall have remedy by a civil action against the Director filed in the United States District Court for the District of Columbia within 180 days after the grant of the patent. Chapter 7 of title 5, United States Code, shall apply to such action. Any final judgment resulting in a change to the period of adjustment of the patent term shall be served on the Director, and the Director shall thereafter alter the term of the patent to reflect such change."

Given that the above-quoted law expressly gives the United States District Court for the District of Columbia jurisdiction and authority over the PTO with regard to PTA, the PTO is not at liberty to not follow this District Court. Reconsideration of the Dismissal is respectfully requested on this basis.

Patentees have recalculated PTA for the captioned patent under the court's interpretation of the PTA statute, and have determined that the patent is entitled to 460 days PTA, as shown on the attached sheet, which shows the relevant delays under 37 CFR §§1.702(a) and (b), and under 37 CFR §§1.703(a) and (b).

The attached sheet details the circumstances during the prosecution of the application resulting in the patent that constitute a failure to engage in reasonable efforts to conclude processing or examination of such application as set forth in § 1.704.

(a) Total of non-overlapping PTO delay under §154(b)(1)(A) & (B):	657 days
(b) Total Applicant delay:	197 days
Final PTA Determination:	460 days

Patentees therefore respectfully request that the patent be accorded 460 days PTA.

The patent is not subject to a terminal disclaimer.

Patentees are not aware of any specific regulatory authority requiring the Patent Office to issue a decision within any specific time period. In the interest of judicial and administrative economy and efficiency, it is respectfully requested that a decision on this present request for reconsideration be deferred or delayed until a final decision has been rendered in Wyeth v. Dudas, which is now on appeal at the U.S. Court of Appeals for the Federal Circuit, under Federal Circuit Docket No. 2009-1120. Thus, holding a decision in abeyance is believed to be appropriate here.

No additional fees are believed to be required. However, if any additional fees are required, the Commissioner is authorized to make appropriate charges to Deposit Account No. 19-0741 to provide exact payment.

Respectfully submitted,

Date November 24, 2009

By _____

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Docket Number: 029860-0154
Application Number: 10/774887
Patent Number: 7427401

	Event Description	Event Date	Days from Filing	PTO Days	Applicant Days
Edit Delete	Application Filing Date	02/09/2004	0		
Edit Delete	Preliminary Amendment under 1.704(c)(6) Received at PTO	03/08/2004	28		
	14 month From Application date	04/09/2005	425		
Edit Delete	Restriction Requirement	05/02/2006	813	388	
	Restriction Requirement + 3 months	08/02/2006	905		
Edit Delete	Restriction Requirement Response Received at PTO	08/15/2006	918		13
Edit Delete	Non-Final Office Action	09/27/2006	961		
	Non-Final Office Action + 3 months	12/27/2006	1,052		
	3 Year Period Starts	02/09/2007	1,096		
Edit Delete	Non-Final Office Action Rsp. Rcv'd at PTO	03/27/2007	1,142		90
Edit Delete	Final Office Action	05/03/2007	1,179		
	Final Office Action + 3 months	08/03/2007	1,271		
Edit Delete	Request For Continued Examination (including amendment)	11/05/2007	1,365		94
	3 Year Period Stopped	11/05/2007	1,365	269	
Edit Delete	Non-Final Office Action	01/15/2008	1,436		
Edit Delete	Non-Final Office Action Rsp. Rcv'd at PTO	04/15/2008	1,527		
Edit Delete	Notice of Allowance	05/19/2008	1,561		
Edit Delete	Issue Fee Paid	08/14/2008	1,648		
Edit Delete	Patent Grant Date	09/23/2008	1,688		
			Totals:	657	197
			PTA:	460	

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OFFICE OF PETITIONS

FOLEY AND LARDNER LLP
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In re Patent No. 7,427,401	:	
Lopez, et al.	:	DECISION ON
Issue Date: September 23, 2008	:	REQUEST FOR RECONSIDERATION
Application No. 10/774,887	:	OF
Filed: February 9, 2004	:	PATENT TERM ADJUSTMENT
Attorney Docket No. 029860-0154	:	

This is a decision on the "REQUEST FOR RECONSIDERATION OF PATENT TERM ADJUSTMENT UNDER 37 C.F.R. §1.705," filed November 12, 2008, requesting that the patent term adjustment determination for the above-identified patent be changed from one hundred ninety-one(191) days to four hundred sixty(460) days.

The request for reconsideration of patent term adjustment is **DISMISSED**.

On September 23, 2008, the above-identified application matured into U.S. Patent No. 7,427,401 with a patent term adjustment of 191 days. This request for reconsideration of patent term adjustment was timely filed within two months of the issue date of the patent. See 1.705(d).

The Office acknowledges submission of the $200.00 fee set forth in 37 CFR 1.18(e). This fee is required and will not be refunded. No additional fees are required.

Patentees request recalculation of the patent term adjustment based on the decision in *Wyeth v. Dudas*, 580 F. Supp. 2d 138, 88 U.S.P.Q. 2d 1538 (D.D.C. 2008). Patentees assert that pursuant to *Wyeth*, a PTO delay under §154(b)(1)(A) overlaps with a delay under §154(b)(1)(B) only if the delays "occur on the same day." Patentees maintain that the period of adjustment due to the Three Year Delay by the Office, pursuant to 37 CFR § 1.703(b), of 269 days and the period of adjustment due to examination

delay, pursuant to 37 CFR §1.702(a), of 388 days do not overlap as these periods do not occur on the same day.

The 269 day period is calculated based on the application having been filed under 35 U.S.C. §111(a) on February 9, 2004, and a request for continued examination (RCE) having been filed in this application on November 5, 2007, three years and 269 days later. Patentees assert that in addition to this 269 day period, they are entitled to a period of adjustment due to examination delay, pursuant to 37 CFR §1.702(a), of 388 days for the failure by the Office to mail at least one of a notification under 35 U.S.C. 132 not later than fourteen months after the date on which the application was filed under 35 U.S.C. 111(a), pursuant to § 1.702(a)(1). A restriction requirement was mailed on May 2, 2006, 14 months and 388 days after the application was filed on February 9, 2004.

Under 37 CFR § 1.703(f), applicants are entitled to a period of patent term adjustment equal to the period of delays based on the grounds set forth in 37 CFR §1.702 reduced by the period of time equal to the period of time during which applicants failed to engage in reasonable efforts to conclude prosecution pursuant to 37 CFR §1.704. In other words, the period of Office delay reduced by the period of applicant delay. The period of reduction of 197 days for applicant delay is not in dispute.

Patentees do not dispute that the total period of Office delay is the sum of the period of Three Years Delay (269 days) and the period of Examination Delay (388 days) to the extent that these periods of delay are not overlapping. However, in effect, Patentees contend that no portion of the Three Year Delay period overlaps with the period of 14 month examination delay. Accordingly, Patentees submit that the total period of adjustment for Office delay is 657 days, which is the sum of the period of Three Year Delay (269 days) and the period of Examination Delay (388 days), reduced by the period of overlap (0 days).

As such, Patentees assert entitlement to a patent term adjustment of 460 days (269 + 388 reduced by 0 overlap - 197 (applicant delay)).

The Office agrees that as of the filing of the RCE on November 5, 2007, the application was pending 3 years and 269 days after its filing date. The Office agrees that the action detailed

above was not taken within the specified time frame, and thus, the entry of a period of adjustment of 388 days is correct. At issue is whether Patentees should accrue 269 days of patent term adjustment for the Office taking in excess of three years to issue the patent, as well as, 388 days for Office failure to take a certain action within a specified time frame (or examination delay).

The Office contends that 269 days overlap. Patentees' calculation of the period of overlap is inconsistent with the Office's interpretation of this provision. 35 U.S.C. 154(b)(2)(A) limits the adjustment of patent term, as follows:

> to the extent that the periods of delay attributable to grounds specified in paragraph (1) overlap, the period of any adjustment granted under this subsection shall not exceed the actual number of days the issuance of the patent was delayed.

Likewise, 37 CFR 1.703(f) provides that:

> To the extent that periods of delay attributable to the grounds specified in §1.702 overlap, the period of adjustment granted under this section shall not exceed the actual number of days the issuance of the patent was delayed.

As explained in *Explanation of 37 CFR 1.703(f) and of the United States Patent and Trademark Office Interpretation of 35 U.S.C. 154(b)(2)(A)*, 69 Fed. Reg. 34283 (June 21, 2004), the Office interprets 35 U.S.C. 154(b)(2)(A) as permitting either patent term adjustment under 35 U.S.C. 154(b)(1)(A)(i)-(iv), or patent term adjustment under 35 U.S.C. 154(b)(1)(B), but not as permitting patent term adjustment under both 35 U.S.C. 154(b)(1)(A)(i)-(iv) and 154(b)(1)(B). Accordingly, the Office implements the overlap provision as follows:

> If an application is entitled to an adjustment under 35 U.S.C. 154(b)(1)(B), the entire period during which the application was pending (except for periods excluded under 35 U.S.C. 154(b)(1)(B)(i)-(iii)), and not just the period beginning three years after the actual filing date of the application, is the period of delay under 35 U.S.C. 154(b)(1)(B) in determining whether periods of delay overlap under 35 U.S.C. 154(b)(2)(A). Thus, any days of

> delay for Office issuance of the patent more than 3 years after the filing date of the application, which overlap with the days of patent term adjustment accorded prior to the issuance of the patent will not result in any additional patent term adjustment. See 35 U.S.C. 154(b)(1)(B), 35 U.S.C. 154(b)(2)(A), and 37 CFR § 1.703(f). See *Changes to Implement Patent Term Adjustment Under Twenty Year Term; Final Rule*, 65 Fed. Reg. 56366 (Sept. 18, 2000). See also *Revision of Patent Term Extension and Patent Term Adjustment Provisions; Final Rule*, 69 Fed. Reg. 21704 (April 22, 2004), 1282 Off. Gaz. Pat. Office 100 (May 18, 2004). See also *Explanation of 37 CFR 1.703(f) and of the United States Patent and Trademark Office Interpretation of 35 U.S.C. 154(b)(2)(A)*, 69 Fed. Reg. 34283 (June 21, 2004).

The current wording of § 1.703(f) was revised in response to the misinterpretation of this provision by a number of Patentees. The rule was slightly revised to more closely track the corresponding language of 35 U.S.C. 154(b)(2)(A). The relevant portion differs only to the extent that the statute refers back to provisions of the statute whereas the rule refers back to sections of the rule. This was not a substantive change to the rule nor did it reflect a change of the Office's interpretation of 35 U.S.C. 154(b)(2)(A). As stated in the *Explanation of 37 CFR 1.703(f) and of the United States Patent and Trademark Office Interpretation of 35 U.S.C. 154(b)(2)(A)*, the Office has consistently taken the position that if an application is entitled to an adjustment under the three-year pendency provision of 35 U.S.C. 154(b)(1)(B), the entire period during which the application was pending before the Office (except for periods excluded under 35 U.S.C. 154(b)(1)(B)(i)-(iii)), and not just the period beginning three years after the actual filing date of the application, is the relevant period under 35 U.S.C. 154(b)(1)(B) in determining whether periods of delay "overlap" under 35 U.S.C. 154(b)(2)(A).

This interpretation is consistent with the statute. Taken together the statute and rule provide that to the extent that periods of delay attributable to grounds specified in 35 U.S.C. 154(b)(1) and in corresponding §1.702 overlap, the period of adjustment granted shall not exceed the actual number of days the issuance of the patent was delayed. The grounds specified in these sections cover the A) guarantee of prompt Patent and Trademark Office responses, B) guarantee of no more than 3 year

application pendency, and C) guarantee or adjustments for delays due to interference, secrecy orders and appeals. A section by section analysis of 35 U.S.C. 154(b)(2)(A) specifically provides that:

> Section 4402 imposes limitations on restoration of term. In general, pursuant to [35 U.S.C.] 154(b)(2)(A)-(C), total adjustments granted for restorations under [35 U.S.C. 154](b)(1) are reduced as follows: (1) To the extent that there are multiple grounds for extending the term of a patent that may exist simultaneously (e.g., delay due to a secrecy order under [35 U.S.C.] 181 and administrative delay under [35 U.S.C.] 154(b)(1)(A)), the term should not be extended for each ground of delay but only for the actual number of days that the issuance of a patent was delayed; See 145 Cong. Rec. S14,718[1]

As such, the period for over 3 year pendency does not overlap only to the extent that the actual dates in the period beginning three years after the date on which the application was filed overlap with the actual dates in the periods for failure of the Office to take action within specified time frames. In other words, consideration of the overlap does not begin three years after the filing date of the application.

In this instance, the relevant period under 35 U.S.C. 154(b)(1)(B) in determining whether periods of delay "overlap" under 35 U.S.C. 154(b)(2)(A) is the entire period during which the application was pending before the Office, from February 9, 2004, as terminated by the filing of the RCE on November 5, 2007. 388 days of patent term adjustment were accorded prior to the issuance of the patent for the Office failing to respond within a specified time frame during the pendency of the application. All of the 269 days for Office delay in issuing the patent overlap with the 388 days of Office delay. During that time, the issuance of the patent was delayed by 388 days, not 388 + 269 days. The Office took 14 months and 388 days to issue a first Office action. Otherwise, the Office took all actions set forth in 37 C.F.R. § 1.702(a) within the prescribed timeframes. Nonetheless, given the initial 388 days of Office

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[1] The AIPA is title IV of the Intellectual Property and Communications Omnibus Reform Act of 1999 (S. 1948), which was incorporated and enacted as law as part of Pub. L. 106-113. The Conference Report for H.R. 3194, 106th Cong. 1st Sess. (1999), which resulted in Pub. L. 106-113, does not contain any discussion (other than the incorporated language) of S. 1948. A section-by-section analysis of S. 1948, however, was printed in the Congressional Record at the request of Senator Lott, See 145 Cong. Rec. S14,708-26 (1999)(daily ed. Nov. 17, 1999).

delay and the 197 days of applicant delay and the time allowed within the time frames for processing and examination, as of the filing date of the RCE, the application was pending three years and 269 days. The Office did not delay 388 days and then an additional 269 days. Accordingly, 388 days of patent term adjustment (not 388 and 269 days) was properly entered since the period of delay of 269 days attributable to the delay in the issuance of the patent overlaps with the adjustment of 388 days attributable to grounds specified in § 1.702(a)(1). Entry of both periods is not warranted. 388 days is determined to be the actual number of days that the issuance of the patent was delayed, considering the 269 days over three years to the filing of the RCE.

Accordingly, at issuance, the Office properly entered no additional days of patent term adjustment for the Office taking in excess of 3 years to issue the patent.

In view thereof, the Office affirms that the revised determination of patent term adjustment at the time of the issuance of the patent is 191 days. No adjustment to the patent term will be made.

Telephone inquiries specific to this matter should be directed to Senior Petitions Attorney Shirene Willis Brantley at (571) 272-3230.

Olivia Brown f/

Nancy Johnson
Senior Petitions Attorney
Office of the Deputy Commissioner
for Patent Examination Policy